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510(k) Summary

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Contact:	Robert S. Anderson, Ph. D. President
Date Summary Prepared:	October 24, 1995
Device Trade Name:	CB Diode/532 Laser System
Common Name:	Dermatology laser system
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.48
Equivalent Device:	LaserScope Aura Laser System (K951034) LaserScope SL Series 12 Watt KTP (K933880)
Device Description:	The CB Diode/532 consists of the laser enclosure and the fiber optic delivery system. The laser enclosure contains the DC Power supply, switching electronics, the laser bench and the Control Panel. The laser bench contains a NdYAG rod pumped by two stacks of diodes rather than the customary flash lamps. The use of diodes to excite the NdYAG rod is a major advance in technology. It increases the over all efficiency of the system while reducing the size and weight of the package. The diodes are also designed for long lifetime thereby reducing the operating costs substantially.

510(k) Summary (cont'd)

Device Description: (cont'd)

In all laser systems operating cw or quasi-cw, a gated pulse is produced by opening and closing a shutter. The shutter is opened for the operator selected exposure time. The use of diodes to pump the NdYAG laser eliminates the need for the mechanical shutter to control the pulse duration. The diodes are switched on and off by an electrical pulse. Lasing occurs only when the diodes are energized. Control of the exposure time is very accurate and not subject to degradation as a mechanical device is. This feature increases both the reliability and safety of the equipment.

The fiber optic delivery system is designed for 400μ, 800μ, and 1200μ fibers. The fiber optic delivery system connects to the laser using a standard SMA connector. The delivery of the laser light from the output of the fiber is controlled by a hand piece, which serves as the aperture.

The Control Panel is an integral part of the laser housing. It connects to a microprocessor which is the brains of the system. The microprocessor monitors all interlocks for safety and set the various parameters selected by the user.

The laser weighs less than 100 pounds, is easily portable. It generally sits on a counter top. It operates on 110 volt power.

Intended Use:

Treatment of cutaneous vascular and pigmented lesions.

Comparison:

Both the LaserScope Aura Laser System and the LaserScope "SL Series Lasers" 12 Watt KTP Laser System emit light at 532nm in a gated pulse mode. Indications for use, target, chromophore, delivery system, spot size, mode of operation, exposure duration, average laser power, energy to lesion aiming beam, laser wavelength, etc. for the ConBio CB Diode/532 Laser System are all within the parameters currently in use by other systems which have been previously found to be substantially equivalent.

510(k) Summary (cont'd)

Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The CB Diode/532 Laser System is substantially equivalent to other existing surgical laser systems in commercial distribution for the treatment of cutaneous vascular and pigmented lesions.
Additional Information:	None requested at this time.